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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,613	06/27/2001	Shawn Shui-on Leung	655	4914

7590 05/09/2007

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
05/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/892,613	LEUNG, SHAWN SHUI-ON	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute; cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/13/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-39 and 50 are cancelled. It is noted that the claims filed 16 February 2007 lacks the requisite status identifiers for all the claims in the application. For example, claims 1-39 were cancelled in the previous amendment filed 28 September 2006 and should be indicated as "(canceled)". The current status of all of the claims in the application, including any previously canceled or withdrawn claims, must be given. See MPEP 714 and 37 CFR 1.121.

Claims 40-49 have been amended.

2. Claims 40-49 are pending and under consideration.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. This Office Action contains New Grounds of Rejections.

Information Disclosure Statement

5. The Information Disclosure Statement (IDS) filed 13 April 2007 has been considered by the Examiner. A signed copy of the IDS is included with this Office Action.

Rejections Withdrawn

6. The objection to the specification in the use of the trademark Rituxan® is withdrawn in view of the amendments to the specification filed 2/16/2007.

7. The objection to claims 41-44 and 46-49 in the recitation "A re-engineered...in view of the amendment to claim 40, which deleted the term "re-engineered" is withdrawn in view of the amendments to the claims.

8. The rejection of claim 45 under 35 U.S.C. 112, second paragraph as being indefinite in the recitation "said donor immunoglobulin sequences" is withdrawn in view of the amendments to the claim.

9. The rejection of claims 40-49 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement as introducing new matter is withdrawn in view of the amendments to the claims.

Response to Arguments

10. The provisional rejection of claims 40-49 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/482,759 is maintained.

The response filed 2/16/2007 requests that this rejection be held in abeyance until the claims of the present application or the co-pending application no. 10/482,759 are allowable. This has been fully considered but is not found persuasive. In view that no terminal disclaimer has been filed and the claims are not in condition for allowance, the rejection is maintained for reasons of record.

11. The rejection of claim 40 under 35 U.S.C. 112, second paragraph as being indefinite in the recitation "the parent immunoglobulin" is maintained.

The response filed 2/16/2007 amends the claim as suggested by the examiner in the previous Office Action, however, it is noted that the claim recites "a parent antibody" not a parent immunoglobulin. Thus, there is insufficient antecedent basis for the limitation "the parent immunoglobulin". The examiner apologizes for the oversight and any inconvenience, however, it is suggested that the claim be amended to "a parent immunoglobulin" for consistency and proper antecedent basis.

New Grounds of Rejections

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 40-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Queen et al (U.S. Patent 5,693,762, issued 12/97, IDS filed 6/27/2001).

It is noted that the prior art of Queen was previously applied in the Office Action mailed 1/7/2003 and is being reinstated in view of the amendments to the claims.

The claims are being interpreted as drawn to a FR-patched immunolgobulin comprising a heavy and light chain from a parent immunolgobulin and FR from a human or primate immunoglobulin and the FR-patched immunoglobulin binds antigen with affinity within 3 fold of the parent, further claimed is the FR chosen exhibits the highest homology to the parent FR, or at least 60% to the corresponding parent FR and the three or four amino acids immediately adjacent to the CDRs are identical or conservatively similar amino acids compared to the corresponding parent FR, and contains identical or conservatively similar amino acids at positions known to be close to or interact with the CDRs as evaluated by computer modeling, crystal structure, or published information, or contains framework residues re-introduced into the antibody which are from the parent immunoglobulin, wherein the affinity is 10^7 M^{-1} to 10^{11} M^{-1}, wherein the immunoglobulin is pure, and a pharmaceutical composition comprising a FR-patched immunoglobulin in a pharmaceutically acceptable carrier. For this rejection the intended use for a pharmaceutical composition is given no patentable weight. Applicant is reminded that the intended use of a product claim carries no patentable weight. See MPEP 2111.02. For this rejection the term "immediately adjacent" is interpreted to be amino acid residues next to a CDR in linear amino acid sequence.

Queen et al teach humanized antibodies wherein the framework regions are from human immunolgobulins and the CDRs are from another species, i.e., mouse. Queen et al teach several criteria for humanization and those are that the human FR is highly homologous, 60-70% (preferably at least 65%) to the corresponding FR of the parental immunoglobulin (i.e., mouse immunoglobulin) (see col. 2, lines 45-55), the human FR residue will be one or more residues that are immediately adjacent to the CDRs, or at 4-

6 Angstroms from the CDR (see col. 3, 14, lines 25-60), or at a position that is rare for the donor relative to the human sequence (see col. 3, lines 20-26), and the affinity is 10^8 M^{-1} or higher and may be within 2 fold of the parent immunoglobulin (see col. 3, lines 35-42), and the FR can have conservative substitutions (see col. 12, lines 20-26), and the antibody comprises amino acids re-introduced from the parental immunoglobulin (i.e., mouse) (see col. 12, lines 39-44), and the immunoglobulins are substantially pure and compositions comprising such. Queen et al also teach the importance of residues immediately adjacent to a CDR or those residues that interact with a CDR which are important for affinity and computer programs to create such models of antibodies (see col. 15, lines 60).

Thus, Queen et al anticipates the claims.

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

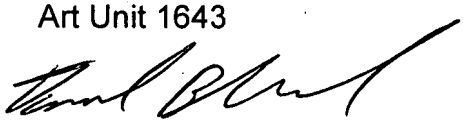
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by

telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J. Blanchard
Patent Examiner
Art Unit 1643



DB
May 4, 2007